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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,805	02/21/2002	William E. Ortyn	BIOL0038	2051

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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,805

Applicant(s)

ORTYN ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-53 is/are pending in the application.
- 4a) Of the above claim(s) 52 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 34-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response, filed May 18, 2005, is acknowledged and has been entered. Claims 1-33 have been cancelled. Claims 34-38, 40, and 41 have been amended. Claims 52 and 53 have been added. Accordingly, claims 34-53 are pending.

2. Newly submitted claims 52 and 53 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 52 and 53 require use of "a set of labeled probes" to define a spectral signature that uniquely identifies a specific component of a cell. Claims 34-51 which are under prosecution require only at least one labeled probe.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 52 and 53 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Currently, claims 34-53 are pending. Claims 34-51 are under examination.

Withdrawn Rejections

3. All rejections not reiterated herein, have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 34-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34, in step a) is vague and indefinite because it is unclear what Applicant intends to encompass in using the term, "feature" as recited in the claim. As an example, the size of an object is a "feature" that can be defined by a labeled probe, but does not appear to encompass Applicant's invention as claimed. Additionally, the specification at pages 6 and 7 uses the terms "feature" and "object" interchangeably. Accordingly, it is unclear how the terms "feature" and "object" should be interpreted in light of the specification. See also claim 42.

Claim 34 is vague and indefinite because it is unclear what Applicant intends to encompass in reciting the terms, "feature" and "object" as recited in the claim. In the specification at pages 6 and 7, the terms "feature" and "object" appear to be used interchangeably. Accordingly, it is unclear how the terms "feature" and "object" should be interpreted in light of the specification.

Claim 34, in step b) is ambiguous in reciting, "if said feature is associated with the object" because the term "associated" is a subjective term that lacks a comparative

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basis for defining its metes and bounds. It is specifically unclear what Applicant intends to encompass in reciting the term "associated", and Applicant has not established nor fully defined in the specification or on the record how the feature element should be associated with the object element. See also claims 42, 43, 47, and 48.

Claim 34, in step b) is indefinite in being contradictory to step a) in reciting, "a plurality of optical signaling components" because step a) recites, "at least one optical signaling component".

Claim 42 is vague and indefinite because it is unclear what Applicant intends to encompass in reciting the terms, "feature" and "object", in all occurrences, as recited in the claim. In the specification at pages 6 and 7, the terms "feature" and "object" appear to be used interchangeably. Accordingly, it is unclear how the terms "feature" and "object" should be interpreted in light of the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The recitation of "feature" in the claims is being interpreted to encompass parts of a cell, such as nucleus, cytoplasm, or specific proteins within a cell. The recitation of "object" in the claims is being interpreted to encompass the cell itself. Accordingly,

5. Claims 34-51 stand rejected under 35 U.S.C. 102(e) as being anticipated by Dunlay et al. (US Patent 6,620,591) for reason of record or as follows.

Dunlay et al. teach a method and cell-based imaging system for detecting features (biomolecules, proteins, antigen, DNA) in objects (cells) to determine biological activity and function in the cells. Dunlay et al. disclose exposing at least one labeled probe (fluorescently-labeled antibody) having a binding element, i.e. antibody, and an optical signaling component (fluorophore or luminophore) to a target feature upon which the antibody specifically and selectively binds (see column 4, lines 6-24). Dunlay et al. teach that a plurality of fluorescent dyes or labels may be used and filter settings and fluorescent channels in the imaging system are specified to match the different desired features to be detected (see column 6, lines 33-52). Light is collected from the object or cell along a collection path, and then focused to produce image corresponding to the object (see page 4, line 40 to column 5, line 10). Dunlay et al. disclose detecting specific fluorescent signals produced from the labeled-probe bound to the specific target feature, then imaging the signals at a low resolution of a few microns per pixel for high throughput and at a higher resolution of less than 0.5 microns per pixel to obtain a plurality of images at specific locations. The images can be optically discriminated. Dunlay et al. teach analyzing the plurality of signals and images produced to determine the presence of fluorescent-labeled probes that are bound to the desired specific target

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features, i.e. nucleus, cytoplasm mitochondria, etc. (see column 5, lines 30-64 and columns 7 and 8). In column 4, lines 26-33 and columns 7 and 8, Dunlay et al. also teach determining fluorescent intensities of wavebands indicative of the fluorescent-labeled probes, their fluorescent domains, and any changes that occur within an emission or excitation spectra. Dunlay et al. further disclose using at least two fluorescent-labeled probes in the method (see claims 1, 7, and 10-15).

Response to Arguments

6. Applicant's arguments filed May 16, 2005 have been fully considered but they are not persuasive.

A) Applicant argues that the term "feature" as used in the claim is clear and definite because the term "feature" is synonymously used in the specification with the term "component". Accordingly, use of the term "feature" in light of the teaching of the specification should be clear and not confusing.

In response, a provision of 35 USC 112, second paragraph is for the specification to conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention. In this case, the term "feature", if intended to define a component of a cell, i.e. nucleus, protein, as supported by the specification should be recited as a component of the cell. Alternatively, "size" of a cell which is a "feature" that can be defined by a labeled probe, does not appear to encompass Applicant's invention as claimed. Additionally, the specification at pages 6 and 7 uses the terms "feature" and "object" interchangeably and synonymously.

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Accordingly, claim 34, step a) as currently recited is indefinite and therefore, this rejection is being maintained for reasons of record.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "feature" in the rejected claims is used to intend "cellular components", while in the specification is used interchangeably and synonymously with the term "object", and the accepted meaning is broadly, any characterization used to define a material, in this case, not limited to a cell. The term is indefinite because the specification does not clearly redefine the term.

B) Applicant argues that there is no ambiguity in the simultaneous use of the terms "object" and "feature" in the claims if read in light of the specification because the terms "object" and "feature" are adequately described in the specification.

In response, Applicant's argument is not on point. Claim 34 is rendered vague and indefinite because it is unclear what Applicant intends to encompass in using the terms, "feature" and "object" as recited in the claim. Descriptive support in the specification at pages 6 and 7, provides apparent consonance between the terms "feature" and "object" as they appear to be used synonymously and interchangeably. Accordingly, it is unclear how the terms "feature" and "object" should be interpreted in

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light of the specification. A provision of 35 USC 112, second paragraph is for the specification to conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention. This is not the case in the instant claimed invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "feature" in the rejected claims is used to intend "cellular components" and the term "object" in the rejected claims is used to intend "a cell", while in the specification, "feature" is used interchangeably and synonymously with the term "object", and the accepted meaning of the terms "feature" and "object" is broadly any characterization, i.e. feature, of a material, i.e. object, in this case, not limited to a cell. The term is indefinite because the specification does not clearly redefine the terms.

C) Applicant argues that the term "associated with" has been used in the claim to determine that a particular feature is present in or on a particular object, since the term "in" would have been insufficient and the term "on" would also be insufficient. Applicant specifically contends that there is no evidence that the term "associated with" employed would not have been understood by one of ordinary skill.

In response, a provision of 35 USC 112, second paragraph is for the specification to conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention. In this case, the term "associated with", is not defined or supported in the specification so as to establish the scope of the claimed invention. Further, Applicant has not established anywhere on the record, how the feature element should be associated with the object element.

D) Applicant argues that Dunlay et al. does not teach each and every element of the Applicant's claimed invention and, therefore, claims 34-51 cannot be anticipated by Dunlay et al. Specifically, Applicant contends that Dunlay et al. uses only one type of signaling component for each feature to be probed whereas the present invention uniquely identifies a specific feature using more than one type of signaling component. According to Applicant, the significance of the present invention is that at least one feature is probed using at least two signaling components.

In response to applicant's argument that Dunlay et al. fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., use of more than one type of signaling component to uniquely identify a feature or that at least one feature is probed using at least two signaling components) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Specifically, claims 34

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and 42 recite, "providing at least one labeled probe ... comprises ... at least one optical signaling component". Accordingly, Dunlay et al. reads on the claimed invention.

E) Applicant argues that Dunlay et al. does not teach each and every element of the Applicant's claimed invention and, therefore, claims 34-51 cannot be anticipated by Dunlay et al. Specifically, Applicant contends that in the present invention, data from all probes bound to a specific feature, are collected simultaneously whereas in Dunlay et al., data for each channel must be collected individually.

In response to applicant's argument that Dunlay et al. fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., data from all probes bound to a specific feature, are collected simultaneously) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Specifically, claim 34 only recites, "collecting light from said object along a collection path" and claim 42 recites, "simultaneously detecting light from all optical signaling components", which does not appear to equate specifically to "collecting data from all probes bound to a specific feature simultaneously". Accordingly, Dunlay et al. reads on the claimed invention.

7. For reasons aforementioned, no claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

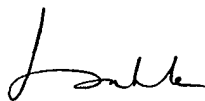
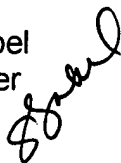
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
July 24, 2005



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07/25/05